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#15

Margaret Brumm
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Patent Division/MMB
Lilly Corporate Center
Indianapolis, IN 46285

Re: GEMZAR™
Docket No. 96E-0314

In re Eli Lilly and Company
U.S. Patent No. 4,808,614
Application for Patent Term Extension

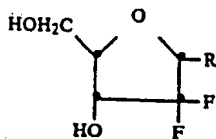
:Decision Dismissing
:Application for Patent Term
:Extension

An application for extension of the term of U.S. Patent No. 4,808,614 ('614) was filed under 35 U.S.C. § 156 in the Patent and Trademark Office (PTO) on July 12, 1996.

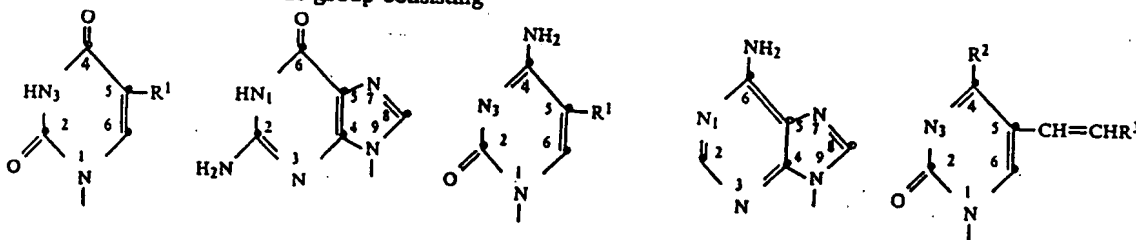
The application is dismissed.

Claim 1 of the '614 patent states:

1. A nucleoside of the formula



wherein R is a base selected from the group consisting of



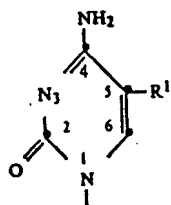
wherein

R¹ is hydrogen, methyl, bromo, fluoro, chloro or iodo;

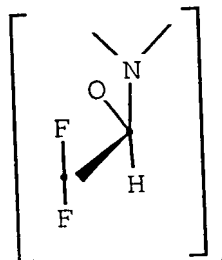
R² is hydroxy;

R³ is hydrogen, bromo, chloro or iodo.

As stated by applicant, when the base R is:



the carbohydrate is in the ribose configuration, the configuration of the juncture between the



ribose and the base is β and R^1 is hydrogen, then claim 1 claims gemcitabine (2'-deoxy-2',2'-difluorocytidine (β -isomer)). Applicant also states that claims 2, 7, 8, 11 and 12, which all depend from claim 1, also claim gemcitabine.

35 U.S.C. § 156 states:

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if-

(4) the product has been subject to a regulatory review period before its commercial marketing or use; . . .

(f) For the purposes of this section:

(1) The term "product" means: . . .

(A) A drug product; . . .

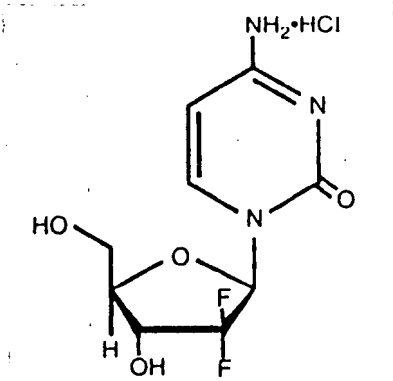
(2) The term "drug product" means the active ingredient of--

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food Drug and Cosmetic Act and the Public Health Service Act) or . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (emphasis added)

Accordingly, one requirement of the statute is that the patent to be extended claim the active ingredient of the drug product which has been subject to regulatory review, its salt or ester. See Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

As confirmed by the March 7, 1997 letter from Ronald L. Wilson, the product in question which has been subject to regulatory review is GEMZAR™, has the active ingredient gemcitabine hydrochloride (the chemical name is 2'-deoxy-2',2'-difluorocytidine mon[d]hydrochloride (β -isomer)). See numbered paragraph one of the application for patent term extension and the product information sheet, Exhibit I, to the application for patent term

extension. Gemcitabine hydrochloride has the following structure:



Gemcitabine hydrochloride is a salt of gemcitabine (2'-deoxy-2',2'difluorocytidine (β -isomer)).

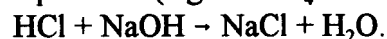
As stated by applicant the '614 patent claims gemcitabine. Gemcitabine, the product claimed in the patent, is not the same as the active ingredient gemcitabine hydrochloride and is neither a salt¹ nor an ester² of the active ingredient gemcitabine hydrochloride. Accordingly, since the '614 patent does not claim either the active ingredient, a salt of the active ingredient, or an ester of the active ingredient, the patent is not eligible for patent term extension under 35 U.S.C. § 156.

In view of the above, the patent is not eligible for patent term extension and the application for patent term extension is dismissed.

A single request for reconsideration of this decision may be made by the applicant within **ONE MONTH** from the date of this letter. See 37 C.F.R. 1.750. Extensions of time under 37 CFR 1.136 are available.

Any correspondence from applicant with respect to this matter should be addressed as follows:

1 A salt is "the compound formed when the hydrogen of an acid is replaced by a metal or its equivalent (e.g. an NH_4^+ radical). Example:



This is typical of the general rule that the reaction of an acid and a base yields a salt and a water." Hawley's Condensed Chemical Dictionary, Twelfth Edition, Van Nostrand Reinold Company, NY.


2 The compound formed by the elimination of water and the bonding of an alcohol and an organic acid.

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